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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,622	09/23/2003	Douglas Mann	PC23253A	2191

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PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
EASTERN POINT ROAD
GROTON, CT 06340

EXAMINER	
STITZEL, DAVID PAUL	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/668,622	MANN ET AL.	
	Examiner	Art Unit	
	David P. Stitzel, Esq.	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *09/23/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RD

OFFICIAL ACTION

Acknowledgment of Receipt

Receipt of the Applicant's Preliminary Amendment to the Specification, dated September 23, 2003, is acknowledged.

Status of Claims

Claims 1-15 are currently pending and therefore examined herein on the merits for patentability.

Information Disclosure Statement

The information disclosure statement (IDS) filed on September 23, 2003, fails to comply with 37 C.F.R. §§ 1.98(a)(2), which requires a legible copy of each and every cited non-patent literature (NPL) publication. More specifically, the aforementioned IDS does not fully comply with the requirements of 37 C.F.R. §§ 1.98(a)(2) because there are ten NPL references cited in the background portion of the instant application, however legible copies of only nine NPL references, which are listed in the IDS, have been provided. In addition, reference numbers (3) and (9), which are respectively cited on the second and third page of the instant application are of particular interest, from an examination standpoint, and therefore copies of which are respectfully requested. Since the submission appears to be *bona fide*, Applicant is given **ONE (1) MONTH** from the date of this notice to supply the above mentioned omissions or corrections in the IDS. NO EXTENSION OF THIS TIME LIMIT MAY BE GRANTED UNDER EITHER 37 C.F.R. § 1.136(a), OR 37 C.F.R. § 1.136(b). Pursuant to 37 C.F.R. § 1.97(i), a failure to timely comply with this notification will result in the aforementioned IDS being placed in the application file without the non-compliant information being considered by the Examiner.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 103, which forms the basis of the obviousness rejections as set forth under this particular section of the Official Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined teachings of U.S. Patent 5,795,881 (hereinafter the Elger '881 patent) and U.S. Patent 4,870,068 (hereinafter the Keister '068 patent).

Claims 1-15 of the instant invention are directed to a method of inducing parturition or farrowing in a near term pregnant swine thereby resulting in the birth of a piglet within a predictable number of hours and reducing the incidence of stillborn piglets, said method comprising administering a progesterone receptor antagonist (PRA) to said near term pregnant swine that is at least 112 days post-conception; wherein said predictable number of hours prior to the birth of said piglet is from about 12 hours to about 40 hours following administration of said PRA; wherein said PRA is administered orally or parenterally by at least one administration in an amount from about 0.001 mg/kg body weight to about 15 mg/kg body weight; wherein said PRA is 11β-[(4-N,N-dimethylamino)-phenyl]-17β-hydroxy-17α-propynyl-4,9(10)-estradien-3-one (a.k.a., mifepristone, RU38486 or RU-486).

It should be noted that the normal gestation period in a pig is 115 days post-conception and that "near term" is recognized in the art of swine breeding as meaning from about day 109 onward in the gestational period. See e.g., the Keister '068 patent (column 2, lines 20-22). It should also be noted that said predictable number of hours prior to the birth of said piglet being *from about 12 hours to about 40 hours* following administration of said PRA according to the instant application was determined by the collective disclosure of claims 2, 9 and 12 of the instant application; wherein claim 2 is directed to said predictable number of hours being *from about 12* hours to about 22 hours; wherein claim 9 is directed to a single administration being administered at approximately 20 hours to approximately 25 hours prior to the birth of said piglet; and wherein claim 12 is directed to a first administration being administered at approximately 30 hours *to approximately 40 hours* prior to the birth of said piglet and a second administration being administered at approximately 9 hours to approximately 15 hours prior to the birth of said piglet.

Similar to claims 1-15 of the instant invention, the Elger '881 patent teaches a method of inducing labor and delivery (abstract; column 2, line 62) in a near or at term pregnant animal (column 3, lines 3-4; and column 5, lines 4-7) thereby resulting in the birth of offspring within a predictable number of hours (column 6, line 54), said method comprising administering a PRA and a progesterone synthesis inhibitor (PSI) to said near or at term pregnant animal (abstract; column 2, lines 65-67; column 3, lines 43-67; and column 4, lines 14-21); wherein said predictable number of hours prior to the birth of said offspring is a maximum of 48 hours following administration of said PRA and said PSI (column 6, line 54); wherein said PRA and said PSI are administered orally or parenterally (column 4, lines 60-67; column 5, lines 1-2; and

column 6, lines 25-26); by at least one administration (column 5, lines 7-12; and column 6, lines 25-26) in an amount from about 5 mg/day to about 200 mg/day (column 4, lines 1-13), and from about 5 mg/day to about 600 mg/day (column 4, lines 36-47), respectively; wherein said PRA is 11β-[(4-N,N-dimethylamino)-phenyl]-17β-hydroxy-17α-propynyl-4,9(10)-estradien-3-one (a.k.a., mifepristone, RU38486 or RU-486) (column 3, lines 49-51) and said PSI is epostane (column 4, lines 38-39).

Similar to claims 1-15 of the instant invention, the Keister '068 patent teaches a method of inducing parturition or farrowing in a near term pregnant sow thereby resulting in the birth of a piglet within a predictable number of hours and reducing the incidence of stillborn piglets (abstract; and column 4, lines 20-37, Table 3), said method comprising administering a PSI to said near term pregnant sow that is at least about 109 days post-conception (column 2, lines 20-22), which encompasses and therefore makes obvious the "at least 112 days" post-conception recitation as set forth in claim 1 of the instant application; wherein said predictable number of hours prior to the birth of said piglet is from about 24 hours to about 48 hours following administration of said PSI (column 2, lines 22-25); wherein said PSI is administered orally or parenterally (column 2, lines 36-45) by at least one administration (column 2, lines 34-36) in an amount from about 1.0 mg/kg body weight to about 20 mg/kg body weight (column 2, lines 32-34); wherein said PSI is epostane (claim 1).

Based on the combined teachings of the aforementioned cited prior art references, it would have been obvious to one of ordinary skill in the art to induce parturition or farrowing in a near term pregnant swine, thereby resulting in the birth of a piglet within a predictable number of hours and reducing the incidence of stillborn piglets, by administering a PRA to said near term

pregnant swine. More specifically, although progesterone receptor antagonists (PRA's) and progesterone synthesis inhibitors (PSI's) induce parturition in a mammal via different mechanisms or modes of action, both ultimately effectuate inducing parturition or farrowing in a near term pregnant mammal by reducing serum progesterone levels in said mammal. Therefore, although the Keister '068 patent does not specifically mention utilizing a PRA to induce parturition in a near term pregnant swine, the Keister '068 patent does explicitly teach utilizing a PSI to induce parturition or farrowing by reducing the serum progesterone levels in said swine. Therefore, it would have been obvious to one of ordinary skill in the art to administer PRA, which ultimately has an identical end result, although via a different mechanism or mode of action, of reducing serum progesterone levels in said swine as does the administration of a PSI, so as to induce parturition or farrowing in a near term pregnant swine. Sufficient motivation, as well as a reasonable expectation of success, exists to combine the aforementioned cited prior art references as said references teach inducing parturition in a near term pregnant animal by reducing serum progesterone levels via the administration of either a progesterone receptor antagonist (i.e., RU38486), or a progesterone synthesis inhibitor (i.e., epostane), or both. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because each and every element of the claimed invention, as a whole, would have been reasonably disclosed or suggested by the teachings of the cited prior art references.

Conclusion

Claims 1-15 are rejected.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David P. Stitzel, Esq. whose telephone number is 571-272-8508. The examiner can normally be reached on Monday-Friday, from 7:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached at 571-272-0887. The central fax number for the USPTO is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published patent applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished patent applications is only available through Private PAIR. For more information about the PAIR system, please see http://pair-direct.uspto.gov. Should you have questions about acquiring access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David P. Stitzel, Esq.

JOHN PAK
PRIMARY EXAMINER
GROUP 1600